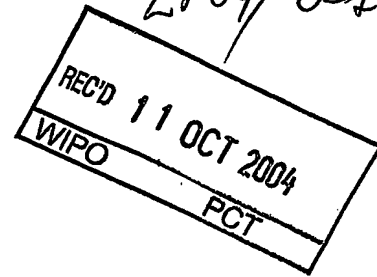


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**Prioritätsbescheinigung über die Einreichung
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Bezeichnung: Unit-dose syringe for a multi-component material

IPC: B 01 F, A 61 C

Die angehefteten Stücke sind eine richtige und genaue Wiedergabe der ursprünglichen Unterlagen dieser Patentanmeldung.

München, den 6. April 2004
Deutsches Patent- und Markenamt
Der Präsident
Im Auftrag

Stromm

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UNIT-DOSE SYRINGE FOR A MULTI-COMPONENT MATERIAL

Description of the Invention (A short description of the invention. Description optionally includes a) summary, b) point(s) of the invention, and c) explanation and problems of current technology. Avoid use of code names, jargon, acronyms, etc. unless defined.)

A unit-dose syringe containing a static mixer for storage, mixing and application of a multi-component dental material is proposed.

Known two-component syringes with static mixers have exchangeable mixing tips to enable multi-dose usage. Those syringes become more and more also available in small sizes for small amounts of material. Usually also the small size syringes have attachable/exchangeable tips - even if the material contained is sufficient for single doses only. The reason for using attachable tips results from the usage of the same 'closure system' for multi- and unit-dose syringes: all syringes are initially closed by caps which have to be replaced with the mixing tips prior to the application of the material.

Especially for unit-dose syringes a considerable part of the total costs results from the closure system mentioned above because additionally to the disposable cap the interconnection between the syringe and the tip requires several movable parts within the mixing tip.

Therefore a unit-dose syringe is proposed providing an integrated and preferably self-opening closure to encapsulate the dental material and to keep the compartments of the material separate during storage. This closure can be easily opened for mixing and application of the material by moving preferably only one part of the syringe.

Utility with Advantages of the Invention (Describe utility of invention, and difference(s) or advantage(s) over previous approaches.)

Dual barrel cartridge

The proposed syringe consists preferably of a cartridge with an integrated manufactured mixing orifice, mixing means and a piston. Known syringes use up to three parts for the mixing tip only, a cartridge, a piston and a cap. So the proposed syringe contains 3 parts instead of 6 which is a much more economic approach for unit-dose systems.

Furthermore all parts can be assembled easily by mounting. Additional gluing or welding processes as they are used for syringes of the prior art are not necessary.

The proposed syringe also includes mixing means, i. e. a static mixer, which allows paste / paste formulations to be mixed homogenous in an easy way without the need to mount a

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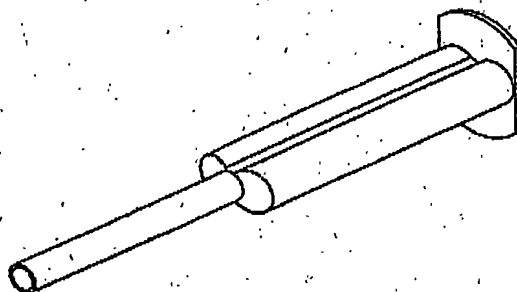
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mixing tip onto the syringe. Also a powder / liquid system approach is proposed at the end of this document.

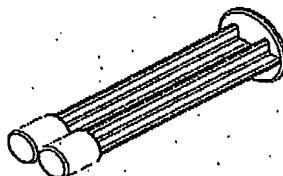
Examples (Provide one or more detailed examples which illustrate the invention. Essential drawings, graphs, or photos which help explain the invention can optionally be included in this section.)

A preferred embodiment comprises:

- a multi-component cartridge with an integral connected mixing orifice.



- A plunger for injecting the material filled in the cartridge, having integral connected pistons engaging in each of the barrels of the multi-component cartridge. The pistons close the barrels of the cartridge on a first end.



- A static mixer which is received in the outlet orifice. The static mixer includes closure plugs which close each of the barrels of the dual cartridge on a second end in order to

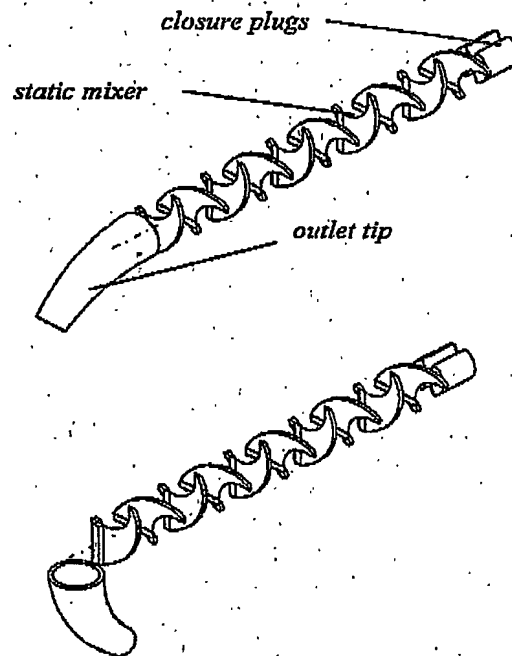
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keep the compartments filled in the syringe encapsulated and separated during storage.

Mixer with integral manufactured outlet tip

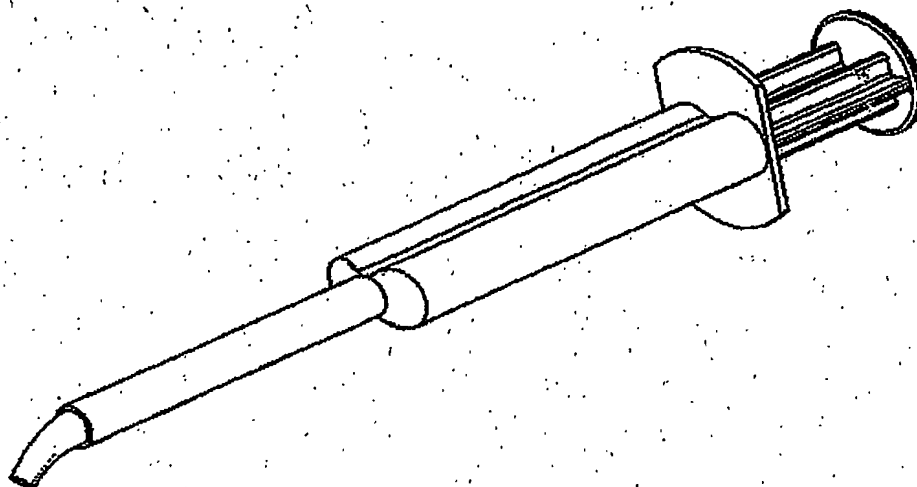
As an option the static mixer can include an integral manufactured outlet tip. For easier molding the tip can be fixed by a hinge construction (right drawing). This construction is advantageous if the mixing helix has to be assembled from the front side of the mixing barrel (occasional necessity of front-assembly of static mixer results from optimized barrel molding).



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Assembled syringe:

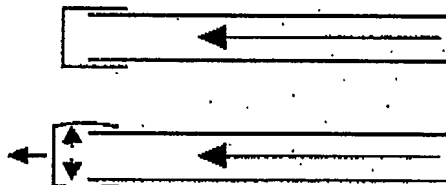


Self-opening mechanism

The syringe is activated by moving the piston into the cartridge. In this case the plugs formed at the static mixer are pushed out of the outlets of the barrels of the cartridge due to hydraulic pressure via the dental material (paste). The mixing helix is enabled to be moved in the longitudinal axis of the mixing barrel within a defined distance.

Option:

Instead of the plugs also flexible caps could be used as a closure for the barrels. In this case the widening of the cap because of the pressure would make the cap easily slide from the barrel.



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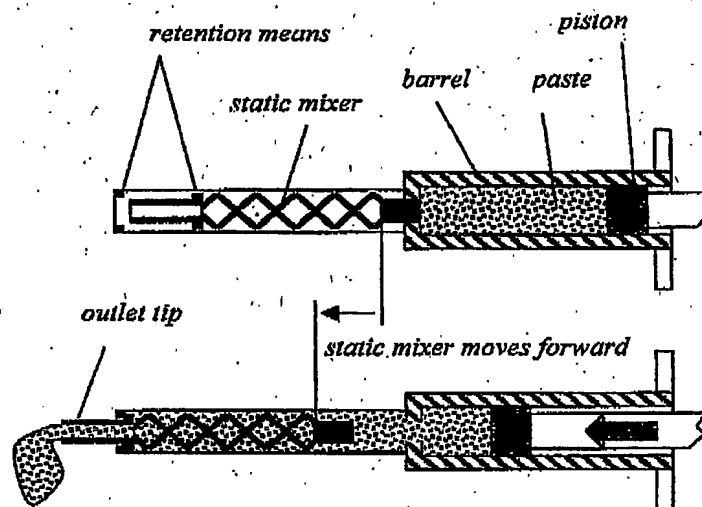
Valve (manual opening mechanism)

Instead of a self-opening mechanism it is also possible to use a valve (i. e. rotary slide valve system) to activate the syringe.

Retention mechanism for front-assembled mixer

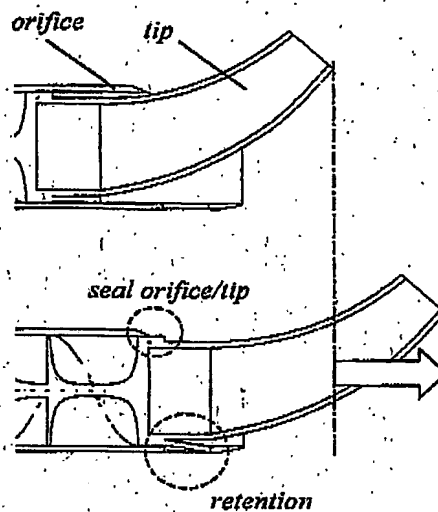
The mixer moves forward until it is stopped by retention means formed at the mixing orifice and the outlet tip which at the same time form a seal between the outer surface of the tip and the inner surface of the orifice thus ensuring the mixed paste flowing through the tip.

Because the plugs are smaller than the inner diameter of the mixing orifice the paste can flow around the plugs and through the mixing helix of the static mixer.

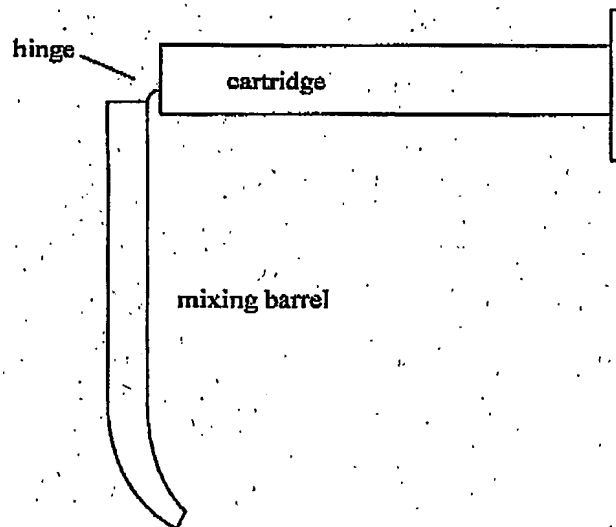


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**Cartridge and mixing barrel with "hinge-connection"**

As an alternative to the mixing helix with integral manufactured outlet tip the tip also could be integrated at the mixing barrel. In order to enable the molding in this case the mixing barrel should be connected to the cartridge via a film hinge.

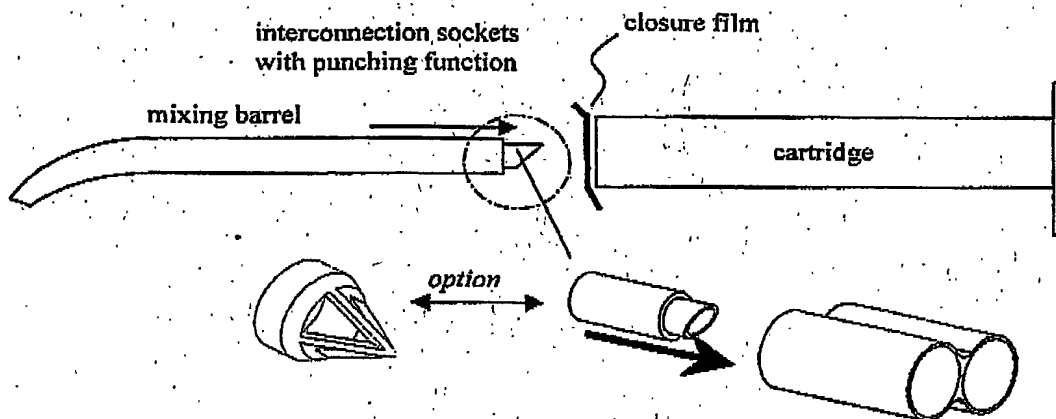


As an option the mixing barrel could also be fixed at the cartridge via plug connections. In this case the mixing barrel would be a separate part and one of the parts, the cartridge

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or mixing barrel, would be featured with interconnection sockets for assembly of the other part respectively.

The advantage of a fold-away or separate mixing barrel is also saving of room (reduced length of syringe) during storage. Furthermore this solution would provide the possibility to make a foil-type cartridge closure rather than the plug closure suggested above in order to improve the storage stability properties. The foil could be made as a peel closure. In a second solution the foil could also be punched through by elements at the mixing barrel during barrel assembly.



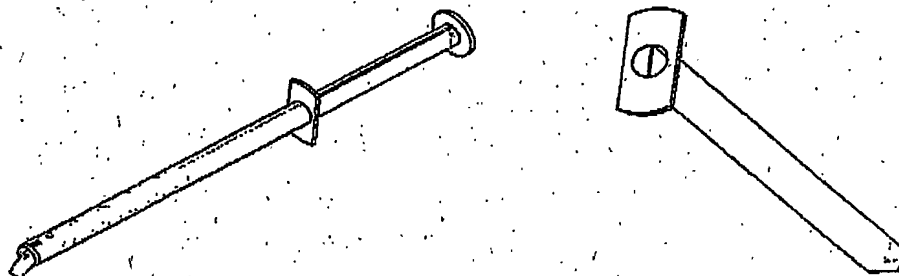
All these solutions mentioned previously would use any kind of retention mechanism for locking the barrel to the cartridge after assembly (snap in solutions).

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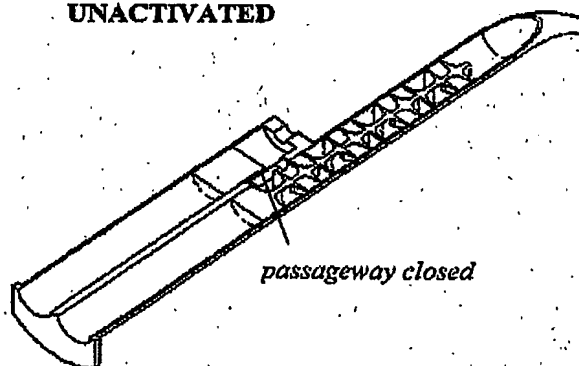
Cartridge as single-barrel with separating walls

In a second embodiment the cartridge has an outer round shape with at least one inner separating walls. As an option the chambers can be arranged concentrically.

Mixing barrel as extension of one of the barrels of the cartridge

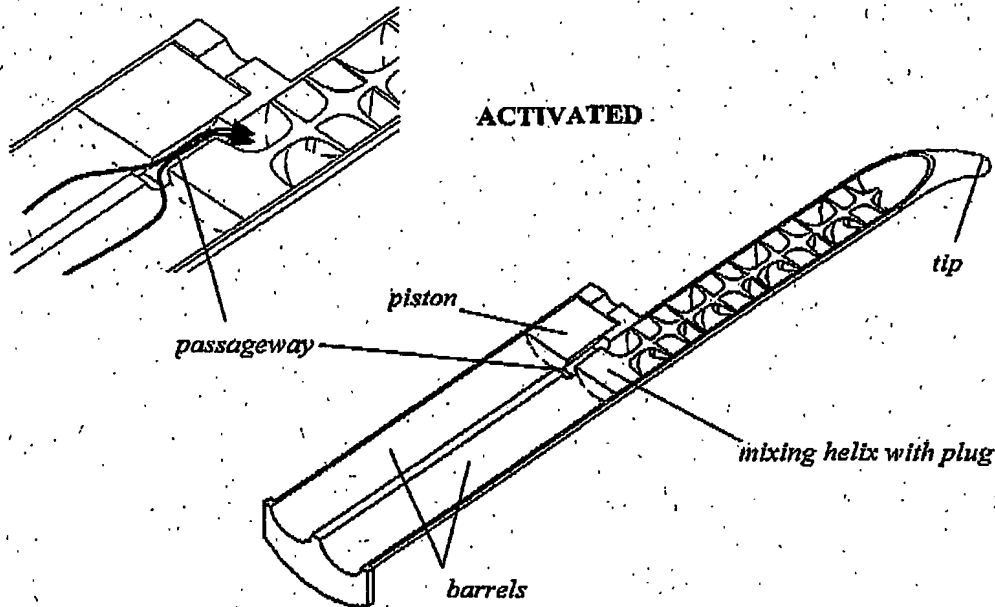
In a third embodiment the cartridge is built of a elongated main barrel and one or more side barrels. The main barrel also forms the mixing barrel preferably with an intra-oral tip. Also for this embodiment a concentrically configuration of the barrels is possible.

The activation of the syringe is done by just moving a dual plunger (not shown) into the syringe. This causes the piston within the side barrel and at the same time the mixing helix with plug to move forward and open a passageway which allows the material compartments flowing through into the mixing barrel (see below).

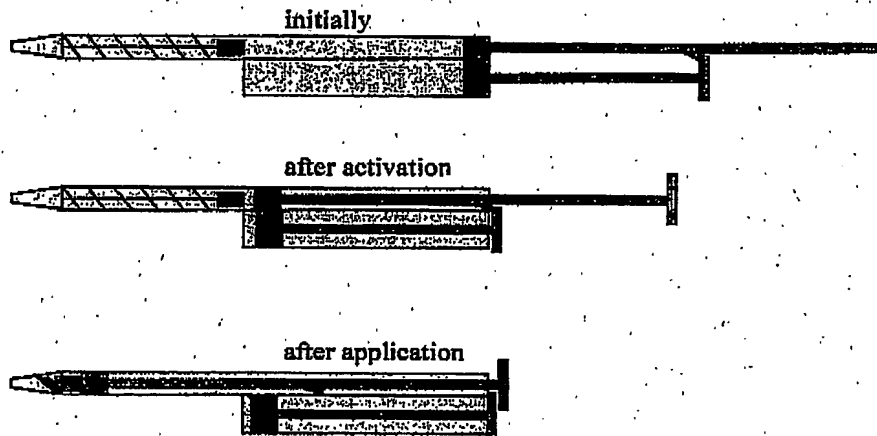
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This solution would also be suitable to be modified for usage of a collapsible mixing helix if the piston construction would be made as follows:



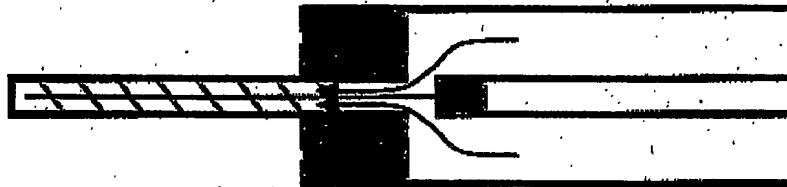
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Different passageways for compartments of significant different viscosity

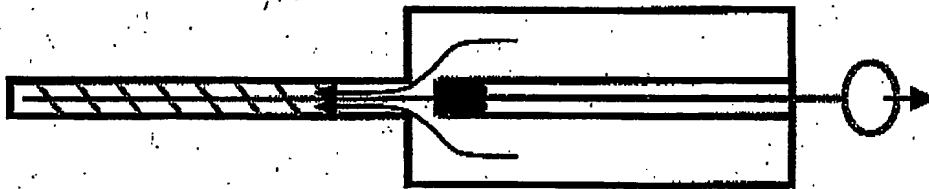
As an option the passageway for the material flow can be split into passageways for each component. Furthermore the passageways can be arranged in different length positions within the barrel in order to cause one or more components to flow over prior to others.

Different diameter for mixing barrel and material barrels

In a further embodiment of the proposed syringe the main barrel can be used as mixing barrel only (no storage of material). In this case the material components are arranged in separate barrels around the mixing barrel (i. e. as separate barrels or concentrically). The mixing helix is then arranged as shown in the drawing below, the plug is used for closing the mixing barrel in the back end direction. This construction can be of advantage if the required diameter of the mixing helix is much more smaller than the diameter of the smallest material barrel because the remaining material within the mixing barrel can be reduced to a minimum. (This construction could also be used with a collapsible mixer. In this case a separate piston for compressing the mixer would be used. This piston - placed within the rear end of the mixing barrel - would be movable independently from the material applicator pistons.)



Alternative (manual) opening mechanism:



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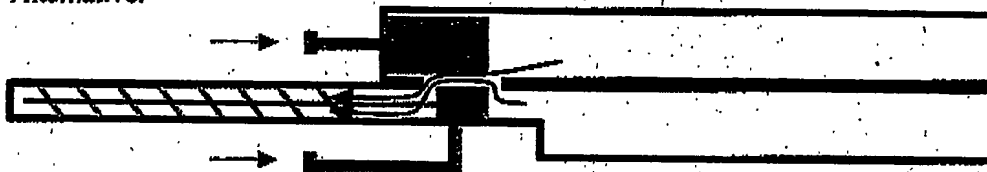
In this solution the closure plugs within the barrels of the cartridge are not necessary. Opening is made by pulling the mixing helix with the closure plug backwards.

Mixing barrel is tapered part of material barrel

A modified construction of this embodiment is shown below. In this alternative the mixing barrel is a tapered part of one of the material containing barrels.

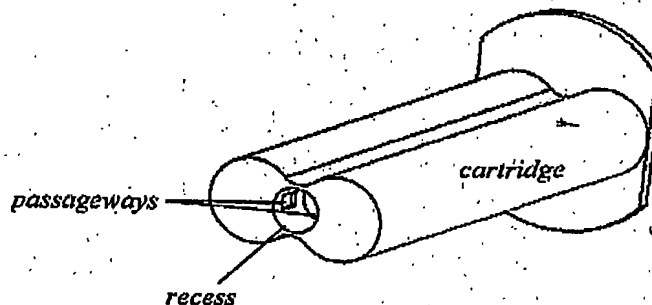


Alternative:



Exchangeable mixing barrel with valve

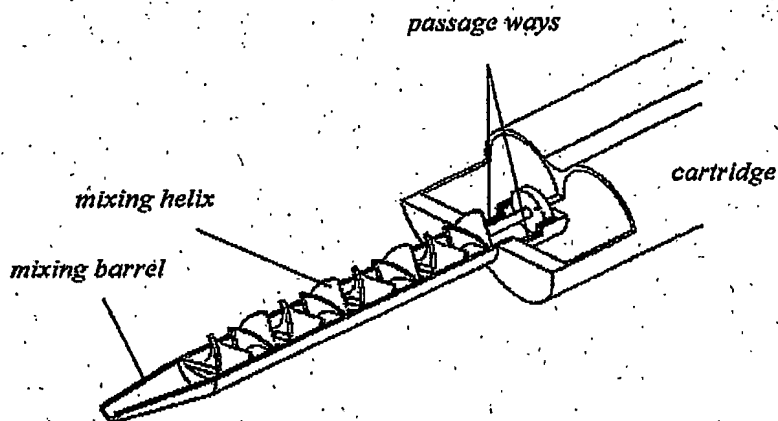
An optional embodiment of the syringe is proposed having a recess in the cartridge for receiving an exchangeable mixing barrel.



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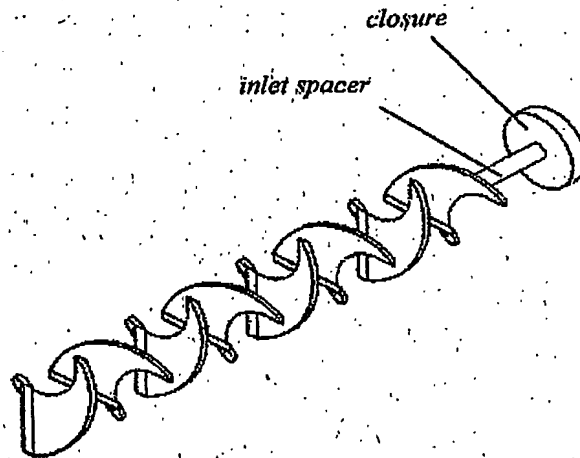
The recess has lateral passageways into the material barrels. The mixing barrel also has passageways which can be aligned to the passageways in the recess thus forming a passageway from the material barrels to the inner channel of the mixing barrel.



The backend of the mixing helix forms a closure for the back end of the mixing barrel. The material compartments can flow through the passageways into the mixing helix where they are mixed homogenously. In the area of the passageways the mixing helix contains an inlet spacer to allow the material easily flowing into the mixing helix.

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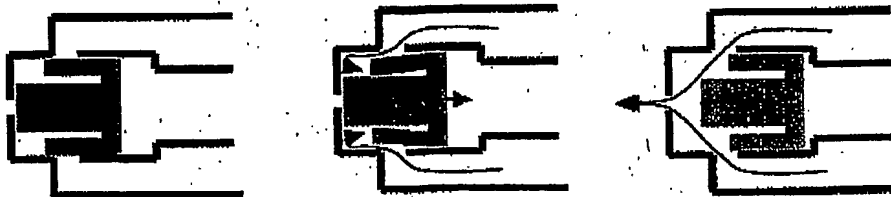
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As an advantage the proposed method of interconnecting the mixing barrel with the cartridge no forces occur in a longitudinal direction between both parts resulting from the material flow because of the lateral passage ways. Even forces in a longitudinal direction between the mixing helix and the mixing barrel are eliminated as the closure part of the helix compensates the forces resulting from the material flow.

An additional advantage is that the connecting system proposed can be used as a valve and opens the possibility to use the proposed syringe as multi-dose system. In this case the mixing barrel can be rotated within the recess until the passageways in the mixing barrel and the passageways in the recess respectively are unaligned thus closing the cartridge. A separate cap for closing the cartridge during storage is not necessary. Further to saving the cap the risk of using a wrong mixer with the material filled in the cartridge will be reduced.

Option for a self-opening valve:



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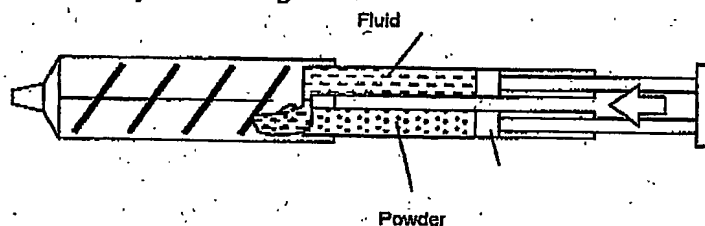
A plug with a flexible lip is deformed by the pressure of the dispensed material thus enabling the material flowing into a chamber. Due to the pressure arising in the chamber a force is arising onto front walls of the lip making the plug move backwards and open a passageway.

Cartridge with integral molded mixing helix

As an option to the latter embodiment the mixing helix can be integral manufactured with the cartridge. This solution may be used for some of the embodiments mentioned above.

Mixing of powder / liquid compositions

Mixing of powder and liquid can be achieved if the liquid chamber of the cartridge is closed on the outlet side. During activation of the syringe the liquid is forced to flow through a small side channel into the powder chamber which is open on the outlet side. Due to the fluid flow the powder will be carried out of the cartridge into the mixing barrel while powder and fluid are pushed consistently by the ram. The pre-mixed powder-liquid-mix is homogenously mixed by the mixing helix. This system would also work in combination with a collapsible mixing helix.

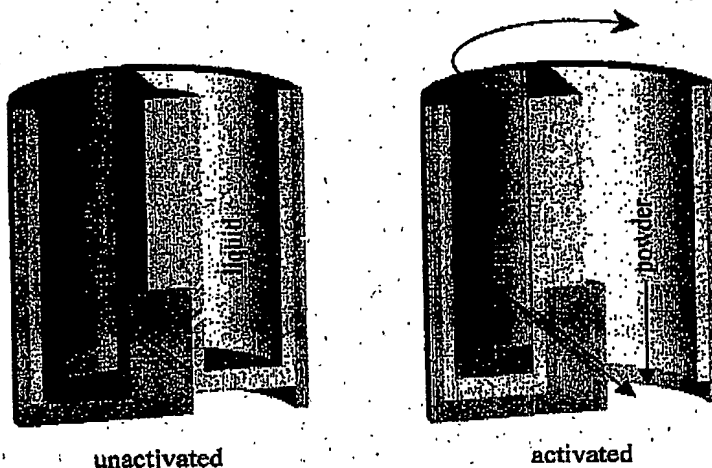


Opening mechanism for powder / liquid syringe

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A double function rotary slide valve can be used as opening mechanism for the powder / liquid syringe. In the unactivated position the angular passageway in the outer container is closed by the inner container. In addition the outer container forms a wall of the powder chamber. By turning the inner container by 180° a bore within the liquid container will be aligned to the passageway thus opening the liquid chamber. At the same time the front wall of the powder chamber is removed thus allowing the powder to easily flow out.

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Application force reduction mechanisms

For all solutions described above mechanisms like threads, gear racks or chain-block-principles can be used in order to reduce the forces required for dispensing material out of the syringe.



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